510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041946

B. Purpose for Submission:
New Device

C. Analyte:
Human Chorionic Gonadotropin (hCG)

D. Type of Test:
Qualitative

E. Applicant:
ACON Laboratories, Inc.

F. Proprietary and Established Names:
ACON® SPECTRUM Urine/Serum Pregnancy Test Device

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155 Human Chorionic Gonadotropin (HCG) test system
2. Classification:
   Class II
3. Product Code:
   JHI
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   The ACON® SPECTRUM Urine/Serum Pregnancy Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.
2. Indication(s) for use:
   The ACON® SPECTRUM Urine/Serum Pregnancy Test Device is intended for the qualitative identification the elevated level of human Chorionic Gonadotropin (hCG) in urine and serum to aid in the determination of pregnancy. It is for healthcare professionals only.
3. Special condition for use statement(s):
   For prescription use.
4. Special instrument Requirements:
   NA

I. Device Description:
The ACON® SPECTRUM Urine/ Serum Pregnancy Test Device is distributed in kits of 25 or 40 per box. Each kit contains the test device, disposable droppers and a package insert. The test device uses both a mouse monoclonal antibody that is conjugated with a proprietary dye-binding system and a goat polyclonal antibody.

The hCG molecule in a urine or serum sample reacts with the monoclonal hCG antibodies-dye conjugate and with the polyclonal hCG antibody on at the test region via capillary migration. A red colored zone in the control (C) region will always be cleared to expose a blue line thus indicating adequate sample volume. A colored line forms in the test (T) region indicates a positive result; while absence of this colored line indicates a negative result.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ACON® hCG Urine/Serum One Step Pregnancy Test Device
2. Predicate K number(s):
   k993065
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	The ACON® SPECTRUM Urine/Serum Pregnancy Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.	For professional use for the qualitative identification of hCG to aid in the determination of pregnancy
Specimen	Urine and Serum	Urine and Serum
Sensitivity	25 mIU/Ml	25 mIU/mL
Storage	2 to 30º	2 to 30º
Principle	Sandwich Immunochromatographic Assay	Sandwich Immunochromatographic Assay
Read Time	Serum: 5 Minutes Urine: 3 Minutes	Serum: 5 Minutes Urine: 3 Minutes

Differences		
Item	**Device**	**Predicate**
Test Line	Particle Membrane Immunoassay	Proprietary Dye-binding Membrane Immunoassay

K. Standard/Guidance Document Referenced (if applicable):

None Referenced

L. Test Principle:

The principle of the device is based upon chromatographic immunoassay technology.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   Eighty-two participants were recruited to test coded, blind and random male serum and urine samples that were spiked with 4 concentrations of hCG of 0, 10, 25 and 100 mIU/mL. While the participants tested samples with both the ACON SPECTRUM test device and the predicate ACON hCG pregnancy test device, only the ACON SPECTRUM Test device is listed in the following chart.

	0 mIU/mL	10 mIU/mL	25 mIU/mL	100 mIU/mL
Urine	46/46 Negative	29/46 Negative	46/46 Positive	45/46 Positive*
Serum	36/36 Negative	32/36 Negative	36/36 Positive	36/36 Positive

*One of the 100 mIU/mL did not have adequate volume necessary for a proper reading.

b. *Linearity/assay reportable range:*
N/A

c. *Traceability (controls, calibrators, or method):*
WHO 4th International Stand for Chorionic Gonadotropin

d. *Detection limit:*
The detection limit for the ACON SPECTRUM test device is 25 mIU/mL.

e. *Analytical specificity:*
Neat Urine and serum samples were spiked with 300 mIU/mL of Luteinizing Hormone (LH), 1000 mIU/mL of Follicle Stimulating Hormone (FSH) and 1000 uIU/mL Thyroid Stimulating Hormone (TSH). Triplicates of each sample was rested using the ACON SPECTRUM test device, and the results were read at 3 minutes and 10 minutes. The results demonstrated no cross results with the above hormones in urine or serum samples.
Prescription, OTC drugs, chemical and biological analytes were added to negative (0 mIU/mL) and positive (25 mIU/mL) spiked urine and serum pools. The samples were visually analyzed with three lots of ACON SPECTRUM Urine/Serum Pregnancy Test Devices in triplicates and read at 3 and 10 minutes for urine and 5 and 10 minutes for serum. None of the analytes tested interfered with the positive or negative hCG urine and serum samples.
Five neat urine pools (totaling 20 samples) with pH that ranged from 5 to 9 were analyzed in duplicates using the ACON SPECTRUM Urine/Serum Pregnancy Test device. While leaving one of the duplicates neat and spiking the other samples with 25 mIU/mL of hCG, the samples were read at three and ten minutes and gave the correct positive and negative test results at pH levels between 5 and 9.
A urine specific gravity study was conducted on urine collected from male volunteers. The specific gravity was measured with a clinical refractometer and ranged between 1.002 and 1.032. The urine was divided into 3 parts- one hCG free aliquot, one spiked with 25 mIU/mL and one spiked with 50 mIU/mL. The samples were tested in duplicates with 3 lots of the ACON SPECTRUM Urine/Serum Pregnancy Test device and read at 3 and 10 minutes. Correct positive and negative results were obtained with all tests at each specific gravity level tested.

A time flexibility study was conducted on 20 spiked male serum samples and 20 urine samples. Each sample was run in replicates of 10 and results were read visually as positive or negative at 1, 2, 3, 4, 5, 10, 30, 60, 8 hours and 24 hours for both serum and urine. Urine samples obtained a 100% read time of 3 minutes in the 10/10 samples tested which corresponds to the read time chosen for the device. Serum samples obtained a 100% read time of 5 minutes which corresponds to the read time chosen for the device.

f. Assay cut-off:

See Detection Limit Above.

2. Comparison studies:

a. Method comparison with predicate device:

Eighty-two participants were recruited to test coded, blind and random male serum and urine samples that were spiked with 4 concentrations of hCG of 0, 10, 25 and 100 mIU/mL. Participants tested samples with both the ACON SPECTRUM test device and the predicate ACON hCG pregnancy test device.

The results are listed in the chart below.

	Urine		**Serum**	
hCG Concentration	**ACON SPECTRUM**	**ACON hCG Urine/Serum One Step**	**ACON SPECTRUM**	**ACON hCG Urine/Serum One Step**
0 mIU/mL	46/46 Positive	46/46 Positive	36/36 Positive	36/36 Positive
10 mIU/mL	29/46 Positive	34/46 Positive	32/36 Positive	22/36 Positive
25 mIU/mL	46/46 Positive	46/46 Positive	36/36 Positive	36/36 Positive
100 mIU/mL	45/45 Positive	46/46 Positive	36/36 Positive	36/36 Positive

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical sensitivity:

The ACON SPECTRUM Urine/Serum Pregnancy Test device was evaluated at 2 clinical/professional sites to ascertain the products accuracy and reproducibility as compared to the predicate.

Site A showed an accuracy of over 99% (174/174 subjects) in the urine specimens with a confidence interval of 98-100%. 84/84 results were correctly positive and 90/90 were correctly negative.

Site B showed an accuracy of over 99% (100/100 subjects) in the serum specimens with a confidence interval of 96-100%. 53/53 results were correctly positive and 47/47 results were correctly negative.

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a and b are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:
   The expected values are based on literature and in previous sensitivity studies that demonstrated adequate performance at the cutoff of 25 mIU/mL.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.